UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

(CV-06-907)

GORDON W. PARKER, Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	Civil Action No. _____ COMPLAINT FOR DAMAGES DEMAND FOR JURY TRIAL

WEINSTEIN, J.

Plaintiff states, alleges, and avers as follows:

PARTIES

1. Plaintiff, Gordon W. Parker is a resident and citizen of the State of Virginia.

2. Defendant Eli Lilly and Company ("Lilly") is an Indiana corporation with its principal place of business in the State of Indiana.

DIVERSITY JURISDICTION & VENUE

3. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a), as Plaintiff is a citizen of a different state than defendant, resulting in diversity jurisdiction, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

4. The Court has specific personal jurisdiction over Lilly pursuant to McKinney's CPLR § 302, and the Court has general personal jurisdiction over Lilly by virtue of Lilly's substantial, continuous, and systematic contacts with the State of New York, unrelated to Plaintiff's claims.

5. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) & (c).

GENERAL ALLEGATIONS

6. In or about October of 2002, Plaintiff was prescribed Zyprexa by Plaintiff's physician.

7. Plaintiff's physician prescribed Zyprexa to treat Plaintiff's mental condition in reliance upon Lilly's representations that Zyprexa was a safe and effective medication for patients afflicted by mental health disorders or illnesses such as Plaintiff's condition.

8. Plaintiff purchased Zyprexa and ingested the Zyprexa in accordance with the prescription, all within the State of Virginia.

9. During and/or subsequent to Plaintiff's ingestion of Zyprexa, Plaintiff was diagnosed with diabetes and diabetes related illnesses.

10. Plaintiff's injury was proximately caused by the ingestion of Zyprexa.

11. As a direct and proximate result of ingesting Zyprexa, Plaintiff now suffers from a chronic, life threatening illness, and has and will suffer past, present, and future injuries, damages, and losses as prayed for below, including but not limited to, physical pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, past, present, and future medical, rehabilitation, and service expenses, and loss of earnings and/or earnings capacity.

12. Zyprexa is a "second generation" antipsychotic pharmaceutical product designed, compounded, manufactured, processed, tested, inspected, packaged, advertised, distributed, marketed, promoted, labeled, licensed and sold in the stream of commerce by Lilly, its authorized agents, representatives, affiliates, and/or joint venturers.

13. Lilly began marketing and selling Zyprexa in 1996.

14. Both prior to and after 1996, numerous medical and scientific literature established that second generation antipsychotic drugs, including Zyprexa, may and will result in

the onset of diabetes, hyperglycemia, glucose intolerance, and ketoacidosis, and/or pancreatitis in those persons who ingest such drugs.

15. Lilly's own pre-marketing clinical trials demonstrated the occurrence of numerous "treatment emergent adverse events" of diabetes, glucose intolerance, hyperglycemia, ketoacidosis and pancreatitis in persons who ingested Zyprexa.

16. Additional clinical trials conducted by Lilly post-market introduction further established a causal link and/or association between the ingestion of Zyprexa and the onset of diabetes, glucose intolerance, hyperglycemia, ketoacidosis and pancreatitis in persons who ingested Zyprexa during those trials.

17. The Federal Food and Drug Administration ("FDA") database and other worldwide adverse event databases include hundreds of diabetes and diabetes related adverse event reports from 1996 to the present demonstrating an association and/or causal link between Zyprexa and such injuries.

18. Lilly has, at all times relevant to this action, had knowledge of the existence of numerous adverse events of diabetes, hyperglycemia, glucose intolerance, ketoacidosis and/or pancreatitis and related adverse events and/or reactions to Zyprexa in foreign countries including the United Kingdom and Japan.

19. Due to Zyprexa's known association and/or casual relationship between diabetes, hyperglycemia, glucose intolerance, ketoacidosis, and/or pancreatitis in early 2002 after only 9 adverse events in Japan and 40 adverse events in the United Kingdom, the foreign regulatory authorities in those countries required Eli Lilly to make changes in its warnings in those foreign countries to warn about the increased incidence of diabetes and/or diabetes related injuries and of the need to conduct clinical testing and monitoring of the patient to prevent against such injuries.

20. Zyprexa is a defective and unreasonably dangerous product unfit for human consumption because it causes serious adverse events including diabetes, hyperglycemia, glucose intolerance, but not limited to ketoacidosis, and/or pancreatitis in persons who ingest it.

21. Notwithstanding defendant's awareness, knowledge, and possession of information that Zyprexa can and does cause diabetes, hyperglycemia, glucose intolerance, ketoacidosis, and/or pancreatitis in persons who ingest said drug, and that Zyprexa is an unreasonably dangerous product, Lilly knowingly, intentionally, recklessly, willfully, and/or negligently failed and refused to warn prescribing physicians, other health care providers, and the consuming public, including Plaintiff, of Zyprexa's dangerous propensity to cause diabetes, hyperglycemia, glucose intolerance, ketoacidosis, and/or pancreatitis in persons who ingest it, until defendant was ordered to do so by the FDA in September 2003.

22. Until ordered to warn of Zyprexa's dangerous propensity to cause diabetes, hyperglycemia, glucose intolerance, ketoacidosis and/or pancreatitis in persons who ingest said drug, Lilly's only mention from 1996 to 2003 of the diabetes risk was "down-played" in the pre-marketing "adverse reactions" literature and section of the package insert where defendant represented, falsely, that diabetes related risks were "Infrequent."

23. In fact, however, Lilly knew and should have known, during the time period 1996 to 2003 that hundreds and thousands of patients who ingested Zyprexa, post-marketing, suffered from diabetes related illnesses as a proximate result of ingesting Zyprexa.

24. Notwithstanding Lilly's awareness and knowledge that hundreds and thousands of patients who ingested Zyprexa had subsequently suffered from diabetes and diabetes related illnesses in its post-market surveillance, Lilly knowingly, intentionally, recklessly, carelessly,

negligently, and willfully failed to warn physicians and/or their patients on the product's labeling, as required by C.F.R. 201.57, of Zyprexa's dangerous propensities and risk of harm.

25. Lilly's motivation in concealing information of Zyprexa's dangerous propensities and risk of harm from physicians and their patients, notwithstanding Lilly's full awareness and knowledge of the diabetes related risks to the users of Zyprexa, was solely profit driven. Since 1996, Zyprexa had grown to be Lilly's most lucrative drug, accounting for nearly 40% of defendant's revenues, with sales equaling $4.28 billion dollars in 2003 alone.

26. Notwithstanding the FDA's order of September 2003, requiring written warnings of diabetes related risks on Zyprexa's labeling, Lilly knowingly, intentionally, recklessly, willfully, and/or negligently delayed for six months until March 1, 2004, before complying with the FDA's directive to send "Dear Doctor Letters" to physicians disclosing the FDA's order requiring Lilly to warn physicians and their patients, on Zyprexa's label, of Zyprexa's dangerous propensities and risks of harm.

27. Defendant's "Dear Doctor Letters" diluted and down-played the seriousness of harm and the nature of the risk of diabetes from the use of Zyprexa and knowingly, intentionally, recklessly, willfully, and/or negligently stated that the relationship between second generation antipsychotic drugs and diabetes related adverse events and/or reactions were "not completely understood."

28. Lilly also knowingly, intentionally, recklessly, and/or negligently misrepresented in its March 1, 2004 "Dear Doctor Letter" that all second generation antipsychotic (SGA's) drugs were associated with an increased risk of diabetes related illnesses, when in fact, Lilly knew and/or should have known that the Consensus Statement, published in the February 2004 edition of *Diabetes Care*, Vol. 27, No. 2, as a result of the November 2003 conference, which

Lilly participated in, disclosed that extensive medical literature concluded that there was an increased risk for diabetes related illnesses connected with the use of Olanzapine (a.k.a. Zyprexa), and another SGA, Clozopine. Further, Clozopine began warnings of this association since 1997, a fact well known to Lilly, which Lilly didn't do until again it was ordered to do so in the last quarter of 2003 through March of 2004 and the present.

29. Lilly admitted in its form 10Q filing with the Securities Exchange Commission ("SEC") in October 2003, one month after the FDA order was issued requiring Lilly to provide written warnings of Zyprexa's dangerous risk of harm and propensity to cause diabetes related illnesses, that defendant had a "long-standing position that the risk of diabetes should be considered among patients with severe mental illness regardless of the medication choice."

30. Lilly has also, at all times relevant to this action, knowingly, intentionally, recklessly, willfully, carelessly, and/or negligently engaged in a systematic campaign to verbally encourage physicians to prescribe Zyprexa "off-label" to patients who suffer from illnesses other than those for which Zyprexa was specifically approved, in order to further increase defendant's profits, without providing any warning of Zyprexa's risk of harm and dangerous propensity to cause diabetes related illnesses in those who ingest Zyprexa.

31. Lilly, and its officers, directors, employees, and agents, all of whom were acting, at all times relevant to this action, within the course and scope of their agency, employment, and ostensible and apparent authority, knew or should have known of Zyprexa's risks of harm and dangerous propensity to cause diabetes, hyperglycemia, glucose intolerance, ketoacidosis, and/or pancreatitis in persons who ingest Zyprexa.

32. Lilly continued, during all times relevant to this action, to knowingly, intentionally, recklessly, willfully, carelessly, and negligently manufacture, market, promote,

advertise, distribute, and sell Zyprexa notwithstanding of defendant's knowledge of Zyprexa's risk of harm and dangerous propensity to cause diabetes, hyperglycemia, ketoacidosis, and/or pancreatitis in persons who ingest said drug.

33. Lilly, at all times relevant to this action, knowingly, intentionally, recklessly, willfully and/or negligently failed and refused to adequately warn physicians prescribing Zyprexa, and persons ingesting it, of Zyprexa's risk of serious harm and dangerous propensity to cause diabetes, hyperglycemia, glucose intolerance, ketoacidosis and/or pancreatitis and of the need to monitor and/or test patients to prevent against such injuries.

34. Lilly's failure to adequately warn of Zyprexa's risk of serious harm and dangerous propensity to cause diabetes, hyperglycemia, glucose intolerance, ketoacidosis and/or pancreatitis made Zyprexa a defective and unreasonably dangerous product.

35. Lilly knowingly, intentionally, recklessly, willfully, and/or negligently concealed from physicians and persons ingesting it, the fact of Zyprexa's serious risk of harm and dangerous propensity to cause diabetes, hyperglycemia, glucose intolerance, ketoacidosis and/or pancreatitis and of the need to monitor and/or test patients to prevent against such injuries.

36. Lilly, to induce the purchase, prescription, and use of Zyprexa, knowingly, intentionally, recklessly, willfully, and/or negligently deceived physicians who prescribed Zyprexa and persons who ingested it, by fraudulently engaging in false and misleading advertising, and promotion campaigns, and stated in the drug's package inserts that Zyprexa was safe, not capable of causing adverse health effects, and was otherwise fit and effective for human consumption.

37. The material representations made by Lilly to induce the purchase, prescription, and use of Zyprexa, by physicians who prescribed Zyprexa and persons who ingested it, were

false, deceptive, and misleading, and Lilly knew of the false, deceptive, and misleading nature of the misrepresentations when the representations were made.

38. Physicians who prescribed Zyprexa and persons who ingested it, reasonably relied upon Lilly's false and misleading misrepresentations.

39. More specific facts concerning the design, nature, scheme, and course of performance of Lilly's campaign to conceal and misrepresent Zyprexa's serious risk of harm and dangerous propensities alleged herein are not currently available to Plaintiff because such information is uniquely within Lilly's knowledge, possession, or control and not currently accessible to Plaintiff or persons within Plaintiff's control despite Plaintiff's demand therefore.

40. Plaintiff, who suffers from a serious condition and illness, was ignorant of and had no reasonable basis to be aware of, or suspect, Zyprexa's risk of harm and dangerous propensities before and during the period the Plaintiff ingested the drug, and did not learn of such risks of harm and dangerous propensities of the drug, nor the injuries, damages, and losses Plaintiff suffered as a result of ingesting the drug, until after Plaintiff was diagnosed with diabetes and diabetes related illnesses and was informed that Plaintiff's injury might be caused by Plaintiff's use and ingestion of Zyprexa, which did not and could not occur until sometime after September of 2003 and/or March of 2004 when Eli Lilly made public, at the FDA's urging, that Zyprexa was associated and/or causally related to an increased risk of diabetes, hyperglycemia, glucose intolerance, ketoacidosis and/or pancreatitis.

41. The actions and omissions of Lilly committed at all times relevant herein, were willful and reckless, in conscious disregard of the rights and safety of patients such as Plaintiff, and were motivated by profit, greed, and avarice, all to the detrimental expense of the health,

well-being, and safety of at-risk and incapacitated persons, such as Plaintiff, suffering from mental illnesses or disorders.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
(Strict Products Liability)

42. Plaintiff incorporates by reference the preceding paragraphs numbered 1 through 41 of the Complaint.

43. Lilly placed Zyprexa into the stream of commerce and from in or about October of 2002 Plaintiff ingested Zyprexa as prescribed by Plaintiff's physician.

44. During all relevant times, Zyprexa was defective in its design, manufacture and/or warnings and, as such, was an unreasonably dangerous product, the use of which involves risks of harm not acceptable to a reasonable consumer.

45. As a direct and proximate result of ingesting Zyprexa, an unreasonably dangerous product, Plaintiff has developed Diabetes and has suffered and will continue to suffer other injuries, damages, and losses as alleged herein.

SECOND CLAIM FOR RELIEF
(Negligence)

46. Plaintiff incorporates by reference the preceding paragraphs numbered 1 through 45 of the Complaint.

47. Lilly owed Plaintiff a duty of care to reasonably and prudently design, manufacture, provide proper warnings, advertise, investigate, clinically study, test, label and market Zyprexa as an effective and safe product.

48. Lilly breached its duty of care to Plaintiff in that Lilly failed to design and manufacture and sell Zyprexa as an effective and safe product and further failed to warn the users of Zyprexa of the drug's true and known risk of harm.

49. As a direct and proximate result of Lilly's negligence, Plaintiff has developed diabetes and diabetes related illnesses and has suffered and will continue to suffer other injuries, damages, and losses as alleged herein.

THIRD CLAIM FOR RELIEF
(Negligence *Per Se*)

50. Plaintiff incorporates by reference the preceding paragraphs numbered 1 through 49 of the Complaint.

51. Lilly owed Plaintiff a duty of care imposed by law, pursuant to 21 C.F.R. 201.57, to warn via Zyprexa's labeling, of serious adverse reactions from use of the drug and of the drug's potential safety hazards.

52. Lilly's labeling for Zyprexa, at all times relevant to this action, failed to warn that diabetes, ketoacidosis, hyperglycemia, glucose intolerance, and/or pancreatitis are serious adverse reactions and potential safety hazards associated with ingesting Zyprexa and that physicians should perform testing and/or monitoring to prevent against such injuries. Thus, Lilly breached its duty of care to Plaintiff, imposed by law, by violating 21 C.F.R. 201.57.

53. Plaintiff is a member of the class of persons the particular statute is intended to protect. As a direct and proximate result of Lilly's negligence *per se*, Plaintiff developed diabetes and diabetes related illnesses and has suffered and will continue to suffer other injuries, damages, and losses as alleged herein.

FOURTH CLAIM FOR RELIEF
(Negligent Misrepresentation)

54. Plaintiff incorporates by reference the preceding paragraphs numbered 1 through 53 of the Complaint.

55. Lilly, in the course of its business, negligently misrepresented and communicated to Plaintiff and/or Plaintiff's physician false information upon which they relied for guidance in their decision to select Zyprexa to treat Plaintiff's mental condition.

56. The false information supplied by Lilly to Plaintiff and/or Plaintiff's physician was that Zyprexa was safe, effective, and would not harm or adversely effect Plaintiff's health.

57. In making such misrepresentations, Lilly knew or should have known that the misrepresentations were false and not completely accurate at the time Lilly made the representations as aforestated. As such, defendant failed to exercise reasonable care or competence in obtaining or communicating truthful and accurate information to Plaintiff and Plaintiff's physician.

58. The misrepresentations and false information communicated by Lilly to Plaintiff and Plaintiff's physician were material and Plaintiff and Plaintiff's physician justifiably relied in good faith on Defendant's misrepresentations and false information, to Plaintiff's detriment.

59. As a result of the negligent misrepresentations by Lilly's agents and sales representatives, Plaintiff suffered and will continue to suffer injuries, damages, and losses as alleged herein.

FIFTH CLAIM FOR RELIEF
(Breach of Implied Warranty)

60. Plaintiff incorporates by reference the preceding paragraphs numbered 1 through 59 of the Complaint.

61. Plaintiff purchased and/or ultimately obtained Zyprexa from Lilly.

62. Lilly impliedly warranted that Zyprexa was of merchantable quality and safe and fit for the use for which it was intended.

63. Plaintiff relied on the skill and judgment and implied warranty of Lilly that Zyprexa was of merchantable quality and safe and fit for the use for which it was intended.

64. Contrary to Lilly's implied warranty, Zyprexa was not of merchantable quality and not safe nor fit for the use for which it was intended, in that it had serious risks of harm and dangerous propensities when put to its intended use, and would instead cause severe injuries to users of Zyprexa, including Plaintiff.

65. As a result of Lilly's breach of implied warranty, Plaintiff suffered and will continue to suffer injuries, damages, and losses as alleged herein.

SIXTH CLAIM FOR RELIEF
(Breach of Express Warranty)

66. Plaintiff incorporates by reference the preceding paragraphs numbered 1 through 65 of the Complaint.

67. Plaintiff purchased and/or obtained Zyprexa from Lilly.

68. Lilly expressly warranted in its written literature and advertisements that Zyprexa was safe, effective, fit, and proper for the use for which it was intended.

69. Plaintiff relied on the skill and judgment and express warranties of Lilly that Zyprexa was safe, effective, fit, and proper for the use for which it was intended.

70. The express warranties were untrue, false, and inaccurate in that Zyprexa was not safe, effective, fit, nor proper for the use for which it was intended.

71. As a result of the breach of express warranty by Lilly, Plaintiff suffered and will continue to suffer injuries, damages, and losses as alleged herein.

SEVENTH CLAIM FOR RELIEF
(Fraud)

72. Plaintiff incorporates by reference the preceding paragraphs numbered 1 through 71 of the Complaint.

73. Lilly's agents and sales representatives knowingly and intentionally made material misrepresentations to Plaintiff, Plaintiff's physician, and to the public that Zyprexa was safe for use in treating mental disorders and illnesses such as Plaintiff's mental condition.

74. The misrepresentations by Lilly's agents and sales representatives were in fact false, as Zyprexa is not safe for human consumption, and instead proximately causes diabetes, hyperglycemia, glucose intolerance, ketoacidosis, and/or pancreatitis among a myriad of other injuries and/or adverse side effects.

75. When Lilly's agents and sales representatives made these representations that Zyprexa was safe for use in treating mental disorders and illnesses such as Plaintiff's mental condition, they knew said representations were false, deceptive, and misleading, and made said false representations with the intent to defraud, deceive, and mislead.

76. Plaintiff, Plaintiff's physician, and the public justifiably relied upon the misrepresentations of Lilly's agents and representatives and reasonably believed the misrepresentations to be true, and in justifiable reliance upon these misrepresentations, was induced to prescribe and ingest Zyprexa, respectively.

77. As a result of the fraud of Lilly's agents and sales representatives, Plaintiff suffered and will continue to suffer injuries, damages, and losses as alleged herein.

78. Lilly's reckless and intentional concealment from Plaintiff and Plaintiff's physician that Zyprexa is not safe for human consumption, and causes diabetes, hyperglycemia, glucose intolerance, ketoacidosis and/or pancreatitis was oppressive, extreme, malicious, fraudulent, and outrageous conduct in that such conduct was and is so outrageous in character and so extreme in degree that it goes and went beyond all possible bounds of decency and is atrocious and utterly intolerable in a civilized community.

79. As a direct and proximate result of Lilly's extreme and outrageous conduct, Plaintiff has suffered and continues to suffer serious physical harm and severe emotional distress.

80. As a result of Lilly's outrageous conduct, Plaintiff suffered and will continue to suffer injuries, damages, and losses as alleged herein.

EIGHTH CLAIM FOR RELIEF
(Fraudulent Concealment)

81. Plaintiff incorporates by reference the preceding paragraphs numbered 1 through 80 of the Complaint.

82. Lilly's agents and sales representatives knowingly and intentionally made material, false, and misleading representations to Plaintiff, Plaintiff's physician, and the public that Zyprexa was safe and effective for use in treating mental disorders and illnesses such as Plaintiff's mental condition, and made such misrepresentations for the purpose of inducing Plaintiff to purchase and use Zyprexa.

83. The misrepresentations were in fact false, as Defendant's agents and sales representatives knew Zyprexa is not safe for human consumption, but instead causes diabetes,

hyperglycemia, glucose intolerance, ketoacidosis and/or pancreatitis and as such monitoring and/or testing to prevent against such injuries was required.

84. When these representations were made that Zyprexa was safe for use in treating mental disorders and illnesses such as Plaintiff's medical condition, such representations made by Lilly's agents and sales representatives, knowingly and intentionally concealed and withheld from Plaintiff, Plaintiff's physician, and the public the true facts known to Zyprexa's agents and sales representatives namely, that Zyprexa is not safe for human consumption, and instead causes diabetes, hyperglycemia, glucose intolerance, ketoacidosis and/or pancreatitis and that the use of said medication requires periodic testing and/or monitoring to prevent against such injuries.

85. Lilly had a duty to disclose to Plaintiff, Plaintiff's physician, and the public that Zyprexa is not safe for human consumption, and instead causes and/or is associated with causing diabetes, hyperglycemia, glucose intolerance, ketoacidosis, and/or pancreatitis and requires concomitant testing and monitoring since Lilly had superior knowledge of the true facts concerning the safety and efficacy of Zyprexa, which facts were material to Plaintiffs and Plaintiff's physician's decision to use and properly prescribe Zyprexa, respectively.

86. Plaintiff, Plaintiff's physician, and the public justifiably relied upon Lilly's concealment of the true facts concerning Zyprexa and was thereby induced to use Zyprexa.

87. Had Plaintiff, Plaintiff's physician, and the public known of Lilly's concealment of the true facts concerning Zyprexa, Plaintiff would not have been prescribed Zyprexa, nor would Plaintiff have ingested it and/or had Plaintiff used said medication, proper monitoring and/or testing would have been used such that Plaintiff would not have developed the injury Plaintiff ultimately did develop.

88. As a result of the fraudulent concealment by Lilly's agents and sales representatives, Plaintiff suffered and will continue to suffer injuries, damages, and losses as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

1. General damages, including but not limited to, pain and suffering, mental anguish, emotional distress, and loss of enjoyment of life;
2. Special damages, including but not limited to, medical, incidental, hospital, service, and rehabilitation, costs, and expenses;
3. Loss of earnings and/or earnings capacity and other economic losses;
4. Punitive or exemplary damages;
5. Pre-judgment and post-judgment interest, as provided by law;
6. Attorney fees, costs, and expenses of this action, as provided by law;
7. Treble damages, as provided by law;
8. For such other and further relief, as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as provided by Rule 38 (a) of the *Federal Rules of Civil Procedure*.

Respectfully submitted this 1st day of March, 2006.

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